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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	**PAPER NUMBER**
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,964	LEE ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response and Amendments filed 2 February 2007 is acknowledged and entered. Claims 1, 3-5, and 30 are pending. Claims 2, 6-29, and 31-37 have been cancelled by Applicant. Claims 1, 3-5, and 30 are under examination.

2. Rejections and Objections directed to cancelled claims are rendered moot in light of the cancellation of the claims.

Objections to the Specification

3. The objection to Applicant's attempt to incorporate subject matter into this application by reference to GenBank Accession numbers is withdrawn in light of Applicant's arguments and supporting Exhibits, filed.

4. The objection to the disclosure for the misspelling of Alanine and Arginine at p. 18, line 13, is withdrawn in light of Applicant's amendments.

Sequence Compliance

5. The objection to claim 15 for failure to comply with the sequence guidelines is moot in light of Applicant's cancellation of claim 15.

6. The specification is objection to for failure to comply with the sequence guidelines. A sequence is disclosed on page 5, line 2 of the specification without the required reference to the sequence identifiers (SEQ ID NOS:). The specification should be amended so that it complies with 37 C.F.R. § 1.821 which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence, in particular cited amino acid sequences over four amino acids in length. For rules interpretation Applicant may call (571) 272-2510. See M.P.E.P. 2422.04. Applicants are required to amend the specification to comply with 37 C.F.R. §1.821.

Claim Objections

7. The objection to claims 1, 3-5, and 30 because of informalities, is withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. The rejection of claims 1, 3, 4, and 30 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is maintained for the reasons of record and the reasons set forth herein.

The claims continue to recite a peptide comprising a naturally occurring amino acid sequence. Although claim 1 has been amended to recite that the peptide is derived from SEQ ID NO:1, the claims continue to read on naturally occurring peptides comprising the 9 amino acid peptide derived from SEQ ID NO:1 because the term "comprising" encompasses naturally occurring amino acid sequences. Products of nature are non-statutory subject matter. This rejection may be overcome by amending the claims to recite isolated or purified peptides.

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The rejection of claims 1, 3-5, and 30 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the claims have been amended to recite a specific peptide and specific recombinant expression vector comprising a DNA sequence encoding a peptide derived from SEQ ID NO: 1 comprising AKAARQAAR. Applicant's argument has been fully considered, but is not persuasive.

As stated in the Office Action of 21 March 2006, it is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. Applicant's claims, as written, read on a genus of peptides and a genus of recombinant expression vectors comprising SEQ ID NO: 1, but failing to recite any other structural characteristics for

the peptide comprising SEQ ID NO: 1 or the recombinant expression vector comprising a DNA sequence encoding a peptide comprising SEQ ID NO: 1. There is insufficient guidance as to the structure of peptides or recombinant expression vector comprising SEQ ID NO: 1. The claims use the word "comprising," which is "open language." Any peptide or DNA sequence "comprising" (meaning having any other amino acid or nucleic acid sequence on either side of the specified amino acid sequence or DNA sequence encoding SEQ ID NO: 1) would fall within the limitations of the claim. See MPEP 2111.03. Similarly, one of skill in the art would not know how to make a peptide comprising SEQ ID NO:1 without undue experimentation to determine which other sequences may be added to the 9 amino acid sequence of SEQ ID NO: 1, such that SEQ ID NO: 1 will retain its biomolecule transducing function (see instant claim 30). Whether or not any given construct would retain the required function would be unpredictable. It would be unpredictable to determine the structure of a generic polypeptide comprising SEQ ID NO:1 and any other amino acid residues and would require undue experimentation to test the constructs for activity.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. The rejection of claims 1, 3-5, and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. The rejection of claims 1; 3-5, and 30 are rejected under 35 U.S.C. 112, second paragraph, regarding grammatical and idiomatic errors, is withdrawn in light of Applicant's amendments.

16. The rejection of claims 4 and 30 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, is maintained for the reasons of record and the reasons set forth herein.

Applicant's argue that the amendment reciting "in vivo" obviates the rejection. Applicant's arguments have been fully considered, but are not persuasive.

Applicant's recitation of the phrase "in vivo" does not overcome the lack of clarity and the missing steps of the claims. One cannot use the recited routes of administration to, for example, prokaryotic cells. It is unclear whether Applicant's invention is to be administered to a mammal "in vivo" to affect prokaryotic cells in its mouth, gut, or on its skin. Prokaryotic cells do not have muscles by which to receive administration intramuscularly. Prokaryotic cells do not have veins or skin by which to receive administration intravenously or subcutaneously. One can only use these routes of administration in tissues, organs, or subjects, such as animals, mammals, or a particular species of mammal, such as a human. The recitation of "in vivo" in reference to prokaryotic cells only has meaning in the context of gene therapy. Similarly, no targeting moieties are disclosed for eukaryotic cells and it is unclear how Applicant intends to get the claimed peptide sequence to a particular eukaryotic cell by the claimed routes of administration. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

18. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

19. The rejection of claims 1 and 3 under 35 U.S.C. 102(a) as being anticipated by Penn *et al.*, WO01/57277 A2 (published 9 August 2001), is withdrawn in light of Applicant's amendments.

20. The rejection of claims 1, 3-5, and 30 under 35 U.S.C. 102(e) as being anticipated by Narayanan, US Patent 6,780,642 (24 August 2004, priority to 4 August 2000), is maintained for the reasons of record and the reasons set forth herein.

Applicant argues that the '642 patent is not enabled with respect to amended claims 1, 5, and 30. Specifically, Applicant argues that SEQ ID NO: 3 of the '642 patent is not enabled and that the "newly discovered capabilities" of SEQ ID NO: 1 are unappreciated by the '642 patent. Applicant's arguments have been fully considered, but they are not persuasive.

Applicant has failed to establish that the '642 patent is unenabled. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. The '642 patent teaches the claimed peptide comprising a nine amino acid sequence of AKAARQAAR (as residues 1-9 of instant SEQ ID NO: 1 and as residues 558-566 of SEQ ID NO: 3 of the '642 patent). For a sequence alignment, see Supplemental Content search results, database US-10-501-694.rai, Result 1, which is the '642 patent.

It is important for Applicant to understand that the Examiner is reading the claims using the word "comprising" as open language. As such, any protein "comprising" (meaning any amino acid sequence on either side of or encompassing) the 9 amino acid sequence AKAARQAAR, would fall under the phrase "comprising" (see also MPEP 2111.03). As such, the '642 patent also teaches recombinant expression vectors and host cells comprising a DNA sequence encoding a peptide comprising SEQ ID NO: 1 (AKAARQAAR) (see column 5, lines 43-67). Routes of administration are taught at column 28, lines 35-55 (injection in rabbits); column 29, lines 18-42 (in vitro gene therapy); and column 34, lines 13-32 (in vivo gene therapy). The use of conjugates to groups, such as other peptide groups (e.g. for targeting host cell receptors in vivo), or agents facilitating transport across the cell membrane, are taught at column 9, line 35-39. Hybridization-triggered cleavage agents are taught at column 9, lines 41-43. A method of using an expression vector incorporating a SIM2 gene introduced into and expressed in a host cell under conditions that cause SIM2 protein to be produced in the cell are taught at column 27, lines 32-35.

Additionally, case law has established that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347,

51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Also, case law has established that a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore, absent evidence to the contrary, the prior art discloses exactly what is claimed in the instant application.

Because the Patent Office does not have the facilities to determine whether the polypeptide of the '642 patent has the requisite functionality of acting as a transducer, the burden is on the application to show a novel and unobvious difference between the claimed invention and that of the prior art. See In re Brown, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and Ex parte Gray, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

21. In response to Applicant's comment regarding prior art rejections under MPEP 706.02(l), Applicant's representative will appreciate that rejections under 102(a) and 102(e) are separate and distinct statutory requirements, each requiring separate and distinct rejections in order to meet different burdens established by statute and each requiring different requirements to overcome rejections made under the different statutory subsection. For example, MPEP 706.02(a) recites that "[e]ven if the reference is prior art under 35 U.S.C. 102(e), the examiner should still consider 35 U.S.C. 102(a) for two reasons. First, if the reference is a U.S. patent or patent application publication of, or claims benefit of, an international application, the publication of the international application under PCT Article 21(2) may be the earliest prior art date under 35 U.S.C. 102(a) for the disclosure. Second, references that are only prior art under 35 U.S.C. 102(e), (f), or (g) and applied in a rejection under 35 U.S.C. 103(a) are subject to being disqualified under 35 U.S.C. 103(c) if the reference and the application were commonly owned, or subject to an obligation of common assignment, at the time the invention was made. For 35 U.S.C. 102(a) to apply, the reference must have a publication date earlier in time than the effective filing date of the application, and must not be applicant's own work." For further guidance, Applicant's representative is referred to MPEP 706.02(a), 2131, 2132, and 2136. Applicant's representative may also wish to contact the Inventor's Assistance Center for further clarification of patent prosecution procedure. Contact information for the IAC is available through the USPTO's website or at 571-272-1000.

22. Applicant's attention is also drawn to the use of the phrase "claim X is withdrawn," which is used throughout Applicant's Remarks, filed 2 February 2007, when referring to cancelled claims (see especially page 10 of Remarks, regarding claims 13 (second paragraph), claims 12-14 and 16 (third

paragraph), claim 8 (fourth paragraph), which have, in fact been cancelled by Applicant, not withdrawn, as stated in the Remarks. Withdrawn claims are still pending in the case and have not been cancelled. Cancelled claims have been cancelled and are not withdrawn. Applicant's representative is encouraged to review MPEP 714 and 37 CFR 1.121, regarding the proper use of claim status identifiers.

Conclusion

NO CLAIM IS ALLOWED.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward, MA, MS, JD, whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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